

**Notice of Allowability**

Application No.

10/621,206

Applicant(s)

KEALEY ET AL.

Examiner

Hope A. Robinson

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/30/07.
2. ☒ The allowed claim(s) is/are 1,5-17 and 19-21.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit  
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

HOPE ROBINSON  
PRIMARY EXAMINER

Hope A. Robinson  
Primary Examiner  
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**EXAMINER'S AMENDMENT**

1. The previous Final Office Action mailed on October 2, 2007 has been vacated in favor of the following.
2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 20, 2007 has been entered.
3. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.
4. Authorization of this Examiner's amendment was given in a telephone interview with Mr. Ted Apple on November 7, 2007 and via e-mail on November 9, 2007.
5. The Claims have been amended as follows:

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Claim 1 (Currently Amended) A recombinant host cell that produces a polyketide using a starter unit, wherein the recombinant host cell is derived from a native host cell by modification with an expression vector, wherein said expression vector expresses or overexpresses an atoAD enzyme [or a positive transcription regulator that increases the expression of the atoAD enzyme,] and wherein increased expression of the atoAD enzyme results in increased production of the starter unit, wherein the atoAD enzyme is an acetyl-CoA acetoacetate: CoA transferase enzyme designated EC 2.8.3.8 [by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology and having the ability to catalyze the reaction: acetyl CoA + [acetoacetateacetate] acetoacetate  $\leftrightarrow$  acetate + acetoacetyl CoA].

Claim 4 (Cancelled)

Claim 18 (Cancelled)

Claim 19 (Currently Amended) The host cell of Claim [18] 21 wherein the biotin ligase enzyme is encoded by the *birA* gene.

Claim 20 (Currently Amended) A method for producing an analog of 6-deoxyerythronolide B (6-dEB) modified by replacement of the propionate starter unit in a host cell of Claim 1, comprising culturing the host cell under conditions wherein the analog of 6-dEB is produced, and wherein said analog is 14-desmethyl-6dEB, 15-methyl-6-dEB, 15-fluoro-6-dEB, 15-chloro-6-dEB, 15-trifluoro-6-dEB, 15-hydroxy-6-dEB, 14-desmethyl-14-fluoro-6-dEB, 14-hydroxy-6-dEB, 14-desmethyl-14-(methylthio)-6-dEB,

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14-desmethyl-14-chloro-6-dEB, 14-desmethyl-14-hydroxy-6-dEB, 15-(chloromethyl)-6-dEB, 14-ethyl-6-dEB, or 15-ethyl-6-dEB.

Claim 21(New) The host cell of Claim 17, further modified to overexpress a biotin ligase enzyme.

### **EXAMINER'S COMMENTS**

#### ***Withdrawn-Claim Rejection 112***

6. Previous rejections to the claims under 35 U.S.C. 112, first paragraphs enablement and written description are withdrawn by virtue of the amendments made herein.
7. The Restriction Requirement mailed on March 17, 2006 is withdrawn.
8. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance".

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**Conclusion**

9. Claims 1, 5-17 and 19-21 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS

Primary Examiner

*HR*  
*10/1/07*